

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Lisa Scott,

Plaintiff,

v.

Civil No. 13-2616 (JNE/BRT)
ORDER

CSL Plasma, Inc.,

Defendant.

Andrew P. Muller, Muller & Muller, P.L.L.C., and John Klassen, John Klassen, P.A., appeared for Plaintiff Lisa Scott.

Bruce J. Douglas and Stephanie J. Willing, Ogletree, Deakins, Nash, Smoak & Stewart, P.C., appeared for Defendant CSL Plasma, Inc.

Lisa Scott is a transgender woman who attempted to give plasma at a collection center run by defendant CSL Plasma, Inc. (“CSL”) but was rejected because she is transgender. She has asserted a single cause of action against CSL for unlawful discrimination under Section 363A.17 of the Minnesota Human Rights Act (“MHRA”). CSL moved for summary judgment. Although the parties’ arguments at times invoke broader concerns regarding the fairness and propriety of federal guidance on plasma donor eligibility, such policy concerns are not properly before the Court, and the Court does not address them. This decision concerns only whether, in this particular instance and on the record before the Court, there are any genuine disputes of material fact for a jury to consider.

Summary judgment is proper if “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). To support an assertion that a fact cannot be or is genuinely disputed, a party must cite “to

particular parts of materials in the record,” show “that the materials cited do not establish the absence or presence of a genuine dispute,” or show “that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A)-(B). “The court need consider only the cited materials, but it may consider other materials in the record.” Fed. R. Civ. P. 56(c)(3). In determining whether summary judgment is appropriate, a court must view genuinely disputed facts in the light most favorable to the nonmovant, *Ricci v. DeStefano*, 557 U.S. 557, 586 (2009), and draw all justifiable inferences from the evidence in the nonmovant’s favor, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). For the reasons set forth below, the Court denies the motion.

BACKGROUND

The following facts are undisputed. On November 17, 2008, Scott, a male-to-female transgender woman, visited a CSL center in Minneapolis intending to “donate” plasma. CSL compensates plasma “donors” for the time they spend giving plasma, including the pre-donation screening process, and Scott sought that compensation. As Scott went through the standard pre-donation screening steps intended to determine donor eligibility, she met with a CSL nurse (“Nurse”) to discuss her medical history, current medications, and other topics. When the Nurse learned that Scott was taking hormone replacements and had undergone a sex change operation, she designated Scott as permanently ineligible to donate. The Nurse noted in Scott’s file that Scott was permanently rejected “due to sex change operation and hormone replacement medication.”

Scott filed a charge of discrimination with the Minnesota Department of Human Rights (“Department”) on April 20, 2009, and amended the charge in October. The Department then issued a letter stating its determination of probable cause on June 29, 2010. Over three years

later, on July 31 and August 2, 2013, respectively, Scott withdrew her charge and the Department acknowledged the withdrawal. Scott filed the complaint in this action on September 23, 2013.

The MHRA makes it “an unfair discriminatory practice for a person engaged in a trade or business or in the provision of a service” to “intentionally refuse to do business with, to refuse to contract with, or to discriminate in the basic terms, conditions, or performance of the contract because of a person’s . . . sexual orientation . . . , unless the alleged refusal or discrimination is because of a legitimate business purpose.” Minn. Stat. § 363A.17. Sexual orientation encompasses transgender identity. *Id.* § 363A.03, subd. 44.

DISCUSSION

CSL asserted multiple arguments in support of its motion for summary judgment. For different reasons, none succeed.

Statute of Limitations

CSL first argued that Scott’s complaint was untimely, although it acknowledged that no MHRA statute of limitations expressly bars this action. Scott filed both her original charge (April 20, 2009) and an amended charge (October 23, 2009) with the Department within the one-year statute of limitations for filing a charge. Minn. Stat. § 363A.28, subd. 3. The Department then, within twelve months of the filing of the amended charge, issued a letter on June 29, 2010 stating its determination that probable cause existed. *Id.* § 363A.28, subd. 6(b). On July 31, 2013, Scott notified the Department that she was withdrawing her charge in order to file a civil case. She filed the complaint in this action 54 days later.

An aggrieved person may bring a civil action either “within 45 days” after receiving notice that the Department dismissed the charge or reaffirmed a finding of *no* probable cause; or

“after 45 days from the filing of a charge,” unless a hearing has been held or the charging party has signed a conciliation agreement. *Id.* § 363A.33, subd. 1 (emphasis added). If bringing an action after 45 days from the filing of a charge for which the Department determined probable cause exists, “[t]he charging party shall notify the commissioner of an intention to bring a civil action, which shall be commenced within 90 days of giving the notice.” *Id.* § 363A.33, subd. 1(3). Because the Department determined in Scott’s case that probable cause existed, and nothing in the record suggests that a hearing occurred or that Scott signed a conciliation agreement, subdivision 1(3) of Section 363A.33 governed Scott’s charge. She was thus entitled to bring an action after 45 days from the Department’s probable cause determination, as long as she filed her complaint within 90 days of notifying the Department of her intention, which she did. *See State by Beaulieu v. RSJ, Inc.*, 552 N.W.2d 695, 702 n.6 (Minn. 1996) (recognizing that while the statute gives the Department only twelve months to make the probable cause determination, the charging party “may bring [a] civil action after 45 days from [the] filing of the charge”). Scott met her deadlines under the MHRA.

The two cases on which CSL relied, *Beaulieu* and *Powers-Potter v. Nash Finch Co.*, No. 14-cv-0339, 2014 WL 2003063 (D. Minn. May 14, 2014), are distinguishable. *Beaulieu* noted that the statute imposes a twelve-month limitation on the Department to make a probable cause determination, and held that it is per se prejudicial for the Department to miss that deadline by waiting 31 months to make its determination. 552 N.W.2d at 703. *Powers-Potter* also involved agency delay. 2014 WL 2003063, at *1. But CSL did not argue that the Department missed its twelve-month deadline in this case. CSL’s argument that Scott’s delay made this action untimely must be rejected.

Applicability of Section 363A.17 to Plasma “Donations”

CSL argued that donating plasma is not a business transaction and is not covered by Section 363A.17. The Court already rejected this legal argument on CSL’s motion for judgment on the pleadings, and reaffirms its conclusions at this stage. The law provides in relevant part that a “person engaged in a trade or business or in the provision of a service” cannot “intentionally refuse to do business with” or “refuse to contract with” a person “because of” that person’s sexual orientation. Minn. Stat. § 363A.17.

CSL is engaged in the plasma collection business. Its plasma collection centers operate for profit, and CSL sells the plasma “donations” that they collect to another entity for manufacture into pharmaceutical products. CSL also pays plasma donors in exchange for receiving their “donations;” the fact that it technically pays donors for their time spent in the donation process, rather than for their plasma, does not change the fact that it pays them and receives, in exchange, plasma. *See, e.g.*, Muller Supp. Decl. Ex. 1, Dkt. No. 70-1 (acknowledgement by CSL that it pays donors). In this way, CSL is like a resale shop that purchases items from individuals to stock its inventory of merchandise, which the shop sells for profit.

As in its earlier motion, CSL unsuccessfully cited Section 525A.25 of the Minnesota Statutes to argue that the “donation” of plasma cannot be considered a sale of goods or product. Although Section 525A.25 specifies that the use of blood components from living donors is “the rendition of a health care service . . . and is not a sale of goods . . . or a sale of a product,” that provision only applies where the blood or blood components are used “for the purpose of injection, transfusion, or transplantation in the human body.” *Id.* § 525A.25. The definition of source plasma, however, which is what CSL collects from donors like Scott, is plasma collected

for the purpose of manufacturing healthcare products, not for intravenous use. 21 C.F.R. § 640.60. Section 525A.25 therefore does not apply. *See also* April 11, 2014 Order, at 5-6, Dkt. No. 35.

Thus, CSL does business with its plasma donors within the meaning of Section 363A.17, and it refused to do business with Scott when it refused to collect plasma from her in exchange for monetary compensation. CSL alternatively argued that it did business with Scott, because she made it through many steps of the screening process before the Nurse rejected her as ineligible, just like any other potential donor whom CSL rejects based on its medical judgment or federal regulations. However, the first person in the CSL screening process to become aware that Scott was transgender was the Nurse, who then rejected her on that basis.¹ Whether CSL screens out—that is, refuses to do business with—other donors on grounds not susceptible to an MHRA claim is irrelevant.

Standing Arguments

CSL also argued that only an aggrieved plaintiff may bring a claim, and that since Scott has no legal right to donate blood or plasma, she is not aggrieved. A person “is ‘aggrieved’ in the legal sense when she has suffered the denial or infringement of a legal right, and the MHRA allows an aggrieved person to seek ‘redress for an unfair discriminatory practice.’” *Krueger v. Zeman Const. Co.*, 781 N.W.2d 858, 862 (Minn. 2010) (quoting Minn. Stat. § 363A.33, subd. 1). Whether a person has a legal right under the MHRA depends on what the statute provides. “[A]n act of discrimination alone will not satisfy the statutory standing requirement if the language of the MHRA requires more.” *Id.* Thus, CSL’s focus on whether Scott had a “legal right” to donate plasma misses the point. The relevant question is whether, under Section 363A.17(3), an

¹ The fact that Scott progressed through a few stages actually suggests that she might have been eligible to donate if not for the Nurse’s decision based on Scott’s sexual orientation.

alleged act of discrimination by itself “constitutes sufficient injury for the law to provide a remedy,” or whether the statute requires something more. *Id.*

CSL argued that the statute requires something more: the existence of an enforceable contract between the plaintiff and defendant. In *Krueger*, the Minnesota Supreme Court held that the owner of a company could not individually maintain a Section 363A.17(3) claim against an entity that allegedly discriminated against her and her company in the performance of a contract between the two entities. *Id.* at 860, 863-64. Because only the company—and not its owner—was party to the contract, the court held that the owner did not have standing to bring the claim. *Id.* at 864-66. The *Krueger* holding was narrow, pertaining only to the last of the three clauses in Section 363A.17(3): “We hold that Minn. Stat. § 363A.17(3) is unambiguous, and it does not provide a cause of action for a person not a party to a contract, *the performance of which is affected by business discrimination.*” *Id.* at 863 (emphasis added). The holding did not address the separate prohibitions contained in the first two of Section 363A.17(3)’s clauses, which make it illegal “to intentionally refuse to do business with” and “to refuse to contract with” a person on specified grounds. Indeed, the *Krueger* court also recognized that a “person who is denied a contract” could also have standing to sue. *Id.* at 864.

There are a few broadly worded sentences in *Krueger* and subsequent case law that arguably support CSL’s interpretation. For example, *Krueger* stated that “the legislature intended to provide contracting parties with the right to make and perform their contracts without being subject to illegal discrimination. The legislature did not, however, provide remedies to persons other than the contracting parties” *Id.* This *dicta* does not enlarge the scope of its narrow holding, which concerned only alleged discrimination in the performance of a contract. *See also Graphic Comm’ns Local 1B Health & Welfare Fund “A” v. CVS Caremark Corp.*, 850

N.W.2d 682, 690 (Minn. 2014); *Unity Healthcare, Inc. v. Cnty. of Hennepin*, No. 14-CV-114 JNE/JJK, 2014 WL 6775293, at *9-10 (D. Minn. Dec. 2, 2014). Neither the holding in *Graphic* nor in *Unity* enlarged the scope of the *Krueger* rule. See *Graphic*, 850 N.W.2d at 692 (holding concerned a different statute); *Unity*, 2014 WL 6775293, at *10 (holding rested on the finding that the plaintiff’s overly expansive definition of “refus[ing] to do business with” was unsupported and implausible). *Graphic* even acknowledged that the *Krueger* holding concerned whether the statute “creates a private cause of action in favor of a person not a party to a contract for discrimination *in the performance of the contract*.” 850 N.W.2d at 689 (emphasis added). The parties have not cited any cases holding that a plaintiff asserting a “refuse to do business with” claim—as opposed to a “discrimination in the performance of a contract” claim—must allege that she entered into a contract with the defendant.

The plain language of Section 363A.17(3) does not support CSL’s broad interpretation of *Krueger*. The legislature specifically provided that it was illegal to “intentionally refuse to do business with” a person, as well as “to refuse to contract with” a person and to “discriminate in the basic terms, conditions, or performance of the contract” with a person. CSL’s reading would violate the canon of construction that “[w]hen possible, no word, phrase, or sentence should be deemed superfluous, void, or insignificant.” *Krueger*, 781 N.W.2d at 861 (internal quotation marks omitted). Moreover, it would contradict the Legislature’s instruction that “[t]he provisions of this chapter shall be construed liberally for the accomplishment of the purposes thereof,” which include “prohibiting discriminatory business practices.” Minn. Stat. § 363A.04; 1990 Minn. Laws Ch. 567.

Scott has not alleged that CSL discriminated in the performance of a contract with her, so the *Krueger* holding does not apply. She claims that CSL refused to engage in a business

transaction with her. Am. Compl. ¶ 15, Dkt. No. 18. CSL has characterized its relationship with each donor as “private and contractual.” Muller Supp. Decl. Ex. 1. Whether CSL “refuse[d] to do business with” her or “refuse[d] to contract with” her, Scott need not allege that she was party to a contract with CSL in order to assert a cause of action for business discrimination. *Cf. TRI, Inc., v. Boise Cascade Office Prods., Inc.*, 315 F.3d 915, 920 (8th Cir. 2003) (in its analysis of a Section 363A.17(3) claim, characterizing a company’s refusal to purchase office supplies from plaintiff as “a simple refusal to deal, which is a discrete, adverse discriminatory act”). Her allegation of a “refusal to do business with” or “refusal to contract with” discrimination claim “constitutes sufficient injury for the law to provide a remedy.” *Krueger*, 781 N.W.2d at 862.

Legitimate Business Purpose Defense

Scott opposed CSL’s motion on the ground that there are disputed issues of fact regarding the reason CSL rejected her. The parties agreed that the Nurse rejected Scott because she was transgender. The question before the Court is whether there is a genuine dispute as to whether that “discrimination [was] because of a legitimate business purpose.” Minn Stat. § 363A.17(3).

A plaintiff alleging an MHRA violation may survive the defendant’s motion for summary judgment either by offering direct evidence of discrimination or by creating the requisite inference indirectly through the burden-shifting scheme set out in *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973). *Torgerson v. City of Rochester*, 643 F.3d 1031, 1043-44 (8th Cir. 2011) (quoting *Griffith v. City of Des Moines*, 387 F.3d 733, 736 (8th Cir. 2004)); *Gold Star Taxi & Transp. Serv. v. Mall of Am. Co.*, 987 F. Supp. 741, 745-47 (D. Minn. 1997); *Hoover v. Norwest Private Mortgage Banking*, 632 N.W.2d 534, 542 (Minn. 2001). Direct evidence “show[s] a specific link between the alleged discriminatory animus and the challenged decision, sufficient to support a finding by a reasonable fact finder that an illegitimate criterion actually

motivated” the decision. *Torgerson*, 643 F.3d at 1044 (quoting *Griffith*, 387 F.3d at 736); *see also Gold Star*, 987 F. Supp. at 746.

For guidance on which test to apply and how to apply it in this case, the Court looks to case law interpreting MHRA employment discrimination cases and Title VII claims. CSL attempted to distinguish Section 363A.17 from other provisions in the MHRA, including its employment discrimination provision, on the asserted grounds that Section 363A.17 uniquely contains “an express defense: a ‘legitimate business purpose.’” Def.’s Reply 3. Presumably CSL also intended to steer the analysis away from cases interpreting those other MHRA sections and looking to cases interpreting similar federal statutes for guidance. But Section 363A.17 is not the only MHRA provision to include a built-in, statutory defense. For example, the MHRA employment discrimination provision expressly provides the bona fide occupational qualification defense to employment discrimination. Minn. Stat. § 363A.08, subd. 2. The Court accordingly finds that this case law is instructive, as is case law involving Title VII, to the extent that it analyzes the applicable burdens and burden-shifting tests that apply where, as with Section 363A.17(3), the statute provides an express defense to discrimination. *See Torgerson*, 643 F.3d at 1043 (“The same analysis applies to both MHRA and Title VII claims.”); *Gold Star*, 987 F. Supp. at 745.²

Scott argued that the record contains direct evidence that CSL, through the Nurse, rejected Scott as a donor because she was transgender. *E.g.*, Willing Decl. Ex. I, at CSL00206

² At the hearing on CSL’s motion, the Court asked the parties who bears the burden. In supplemental briefing, CSL cited one unpublished opinion applying the *McDonnell Douglas* analysis to a Section 363A.17 claim, but acknowledged that the “legitimate business purpose” defense could be viewed as an affirmative defense. CSL pleaded it as a defense. Dkt. No. 19, at 6 ¶ 8. Scott’s attorney asserted that CSL has consistently argued that the *McDonnell Douglas* test applies (under which Scott would bear the burden of persuasion as to pretext), but Scott argued that she presented direct evidence of discrimination.

(Nurse's notes stating that Scott was rejected "due to sex change operation and female hormone replacement therapy"). CSL did not dispute that the Nurse rejected Scott because Scott was transgender, although it contended that it was justified for various reasons. *E.g.*, Def.'s Supp. Br. 3-5, Dkt. No. 68. Because CSL admitted that it rejected Scott because she was transgender, the Court agrees that Scott has satisfied her burden as to this question. *See Carney v. Martin Luther Home, Inc.*, 824 F.2d 643, 648 (8th Cir. 1987). Refusing to do business with a person because of that person's transgender identity (*i.e.*, sexual orientation, Minn. Stat. § 363A.03, subd. 44) is discrimination under Section 363A.17(3).

But the inquiry cannot end here, *see Carney*, 824 F.2d at 648, because CSL asserted the statutory defense that its "refusal or discrimination [was] because of a legitimate business purpose," Minn. Stat. § 363A.17(3). *See also White v. Dep't of Corr. Servs.*, 814 F. Supp. 2d 374, 384, 387 (S.D.N.Y. 2011) (denying summary judgment on Title VII claim where the parties agreed there was direct evidence of a discriminatory policy, and there were questions of fact regarding a statutory defense); *cf. Ricci v. DeStefano*, 557 U.S. 557, 586 (2009) ("[T]he City made its employment decision because of race The question is not whether that conduct was discrimination, but whether the City had a lawful justification for its race-based action."); *TWA, Inc. v. Thurston*, 469 U.S. 111, 118-19, 121 (1985) (affirming reversal of district court's award of summary judgment for the defendant on federal age discrimination claim where plaintiffs presented direct evidence of discrimination and the defendant failed to establish the bona fide occupational qualification defense).

As with a defendant asserting a statutory bona fide occupational qualification defense, CSL bears the burden of showing that its decision was "because of a legitimate business purpose" within the meaning of that statutory defense. *Cf. Lewis ex rel. Welles v. Metro. Transit*

Comm’n, 320 N.W.2d 426, 430 (Minn. 1982) (employer “must present a factual basis” for an asserted bona fide occupational qualification defense); *Belton-Kocher v. St. Paul Sch. Dist.*, 610 N.W.2d 374, 375 (Minn. Ct. App. 2000) (asking whether defendant showed that its policy was a bona fide occupational qualification under the MHRA); *State, Dep’t of Human Rights v. Hibbing Taconite Co.*, 482 N.W.2d 504, 507 (Minn. Ct. App. 1992) (“The burden then shifted to Hibbing Taconite to prove its decisions not to hire the claimants were justified as a ‘bona fide occupational qualification’ . . .”).

CSL asserted that there is no genuine dispute of material fact as to whether its policy of rejecting transgender donors is “because of a legitimate business purpose.” This assertion, however, is premised on two facts that Scott argued are genuinely disputed: (1) whether, in November 2008, CSL had a policy of rejecting all transgender donors and (2) whether the Nurse’s decision to reject Scott was based on such a policy.

The first question by itself prevents the Court from granting CSL’s motion. CSL details its policies and procedures for determining donor eligibility in a “medical staff reference” (“MSR”) for nurses to consult when screening donors. A new version of an MSR becomes effective—meaning that staff begin using the new reference—only upon the “effective date” listed on its cover. In mid-November 2008, the then-effective MSR, dated November 12, 2007, advised that potential donors undergoing “[h]ormone replacement therapy – including estrogens and androgens” were “[a]cceptable,” and that if a potential donor had had a sex change operation, staff were to “[c]all Corporate Medical Operations” for direction. Willing Decl. Ex. J. About two weeks after Scott visited CSL’s center, CSL implemented an updated MSR, effective December 1, 2008, which contained the new instructions that “in general,” potential donors who reported having had a “Sex/Gender Change” should be permanently deferred, including potential

donors whose “stated gender is different than their ID or previous DMS entries,” who “present legal name change papers which change gender,” who have “previously attempted or donated under a different gender at other blood/plasma centers,” or who, in the case of male donors, “dress as women and/or who take female hormones for the purpose of gender reassignment.” Willing Decl. Ex. K. Under the new policy, only donors “with gender assignment surgery for medical reasons before the age of 12” were acceptable. *Id.*

Thus, as reflected in the November 1, 2007 MSR, CSL did not on November 17, 2008 have a policy mandating deferral of all transgender individuals. Under the November 2007 MSR, the Nurse was supposed to call Corporate Medical Operations to ask what to do with a putative donor like Scott who had had a sex change operation. It is not entirely clear from the record if the Nurse did call. She testified that she did not. Scott testified that the Nurse at one point left the room and told Scott that she called a supervisor, but this testimony does not establish that the Nurse in fact made the call, especially in light of the Nurse’s own contradictory testimony. It is also unclear what the Nurse would have been told if she had called. CSL’s Corporate Medical Director Dr. Toby Simon testified that he recalled “occasions” during the time when the November 2007 MSR was effective when he determined that transgender individuals were acceptable donors. Willing Decl. Ex. C, Simon Tr. 54:23-55:24, Dkt. No. 58-1. Further, according to Dr. Simon, when nurses called Corporate Medical Operations pursuant to the November 1, 2007 MSR with a question about a transgender donor, “responses might not be consistent.” Willing Decl. Ex. D, at 7, Dkt. No. 58-1. CSL theoretically could have presented evidence that each of the doctors fielding Corporate Medical Operations calls on November 17, 2008 would have, in his or her medical judgment, instructed the Nurse to reject Scott, but there is no such evidence in the record before the Court. Finally, although it is true that Scott would not

have qualified as a donor under the December 1, 2008 MSR because she was taking female hormones for the purpose of gender reassignment, the record before the Court does not establish that CSL's nurses or other medical staff did, should have, or would have followed that policy on November 17, 2008.³

In addition, Scott testified that the Nurse physically recoiled when she learned that Scott was transgender and then proceeded to list several behaviors she assumed Scott had engaged in because she was transgender—such as taking drugs and having had sex with other men—before concluding that people of Scott's "type" could not give plasma at CSL. This evidence, which the Nurse's testimony directly controverts, could support an inference that the Nurse acted with personal animus in rejecting Scott.

Therefore, viewed in the light most favorable to Scott, the record before the Court could support a finding by a reasonable jury that on November 17, 2008, CSL did not have a policy of rejecting all transgender donors; that CSL's Corporate Medical Operations might not have told the Nurse to reject Scott; and that the Nurse did not call Corporate Medical Operations and made her decision based on discriminatory animus. Since CSL has not established the existence of a no-transgender-donors policy on the relevant date, the Court cannot grant summary judgment on CSL's asserted defense that a decision made pursuant to that policy was "because of a legitimate business purpose." Likewise, since CSL has not established that any medical staff did or necessarily would have directed the Nurse to reject Scott as a matter of medical judgment, the

³ CSL typically conducts training in advance of an updated MSR's effective date to discuss some of the upcoming changes. It is conceivable that the Nurse, on November 17, 2008, had been trained on the December 1 MSR and based her decision to reject Scott on the soon-to-be-implemented policy. But the record before the Court reveals conflicting testimony on this point. In any event, CSL appears to have abandoned this factual argument, taking the position on this motion that the Nurse consulted the November 2007 MSR and acted accordingly. Def.'s Br. 3 n.3; Def.'s Reply 1.

Court cannot grant summary judgment on the ground that a decision made pursuant to that medical judgment was “because of a legitimate business purpose.”

Nor has CSL established that Scott would have been disqualified as a donor under then-applicable federal regulations or recommendations. Pursuant to a delegation of authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399d, the U.S. Food and Drug Administration (“FDA”) has promulgated regulations that govern the collection of human source plasma, *e.g.*, 21 C.F.R. §§ 610.40-41, 640.60-76 (2015). The FDA has also issued guidance from time to time, including the 1992 memorandum “Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products” (“1992 Recommendations”). *See* Willing Decl. Ex. O, Dkt. No. 58-3. This memorandum provides that “[p]ersons who have engaged in activities that put them at risk of HIV infection”—that is, high-risk donors—“may not be donors.” *Id.* at 7. The “Criteria for the Exclusion of Unsuitable Donors Who Are at Increased Risk for HIV” include “[m]en who have had sex with another man even one time since 1977” and “[p]ast or present intravenous drug users.” *Id.* at 3. In this case, Scott’s testimony that she has never had sex with a man, never used intravenous drugs, and does not in any other respect fit the criteria listed in the 1992 Recommendations is uncontroverted.

In summary, viewed in the light most favorable to her, the evidence that Scott cited in the record raises a genuine issue of material fact as to whether CSL rejected Scott because of a legitimate business purpose. CSL offered abundant support for why, in its view, it is justified as a matter of safety and public health in rejecting transgender donors because, as a population, they are high risk donors. The Court expresses no view as to whether CSL’s justifications would be a legitimate business reason. For all of CSL’s asserted reasons why it can legitimately reject all

transgender donors, it is not clear from this record that, as of November 17, 2008, it *did* reject all transgender donors or that its medical staff made a judgment call in this case to reject Scott. CSL has also not established that Scott was barred by then-applicable federal regulations or guidance from donating. On the record before the Court on this motion, a reasonable jury could find for Scott.

Primary Jurisdiction and Preemption Arguments

Finally, CSL renewed two more arguments that the Court already rejected on CSL's motion for judgment on the pleadings. It contended that recent actions by the FDA reinforced CSL's position.

First, it argued that the FDA has primary jurisdiction over setting plasma donor eligibility standards, and that the Court or a jury cannot decide in Scott's favor without essentially overruling FDA guidance and recommendations and usurping the FDA's role in deciding this public health matter. "Under the doctrine of primary jurisdiction a court *may* leave an issue for agency determination when it involves the special expertise of the agency and would impact the uniformity of the regulated field." *Chlorine Inst., Inc. v. Soo Line R.R.*, 792 F.3d 903, 909 (8th Cir. 2015) (internal citation omitted) (emphasis added).

CSL noted that the FDA released draft guidance in May 2015 specifically addressing the question of transgender donors' eligibility. It asserted that this fact demonstrates that the FDA is still actively considering the very issue in this case: whether transgender individuals should be eligible to donate plasma. *See* Willing Decl. Ex. Q, Dkt. No. 58-3. However, the issue before the Court in the current procedural posture, and the genuinely disputed issue of fact for the jury, is not whether a policy of rejecting all transgender donors for safety reasons is a legitimate business reason for sexual orientation discrimination. Rather, it is the narrow issue of whether

CSL in fact had such a policy when it rejected Scott or whether CSL might have accepted Scott as a donor if the Nurse had called Corporate Medical Operations. This type of factual question is not within the special expertise of the FDA. Further, the recent FDA draft guidance merely proposes that “[i]n instances where a donor has asserted a change in gender identification, medical directors may exercise discretion with regard to donor eligibility.” *Id.* This draft guidance does not govern, much less establish, the facts at issue here: whether CSL had a policy on November 17, 2008, that all transgender donors should be denied as high-risk or rejected Scott in particular because of a medical judgment.

CSL has not persuaded the Court that the questions at issue in this case are more appropriate for the FDA to consider. The FDA has never issued direct guidance on the eligibility of transgender donors and, most recently, has proposed leaving the question within the discretion of medical directors, suggesting that one typical rationale for invoking the primary jurisdiction doctrine—promoting uniformity and consistency—is not compelling in this case. *U.S. v. W. Pac. R. Co.*, 352 U.S. 59, 64 (1956). More significantly, this is not a case in which a court must evaluate the reasonableness of a tariff or the reasonableness of a railroad’s requirement in light of its statutory duty to provide transport upon a reasonable request, in which agency expertise would benefit the court’s analysis. *See id.* at 64; *Chlorine Inst.*, 792 F.3d at 911-12. The narrow question of fact at issue here is not the type of question that requires the FDA’s expertise. To be clear, in denying CSL’s motion for summary judgment, the Court expresses no opinion on whether a plasma collection center today may, in the exercise of medical judgment, decide to reject all transgender donors. A center might be able to establish that it rationally relied on the FDA’s guidance and its own evaluation of the risks to reach a judgment that it was safer to defer all transgender donors, and that reasoning might constitute a legitimate business purpose. But on

this record, there is a genuine dispute as to whether CSL had such a policy as of November 17, 2008 or whether, instead, it might have accepted a transgender donor like Scott had the Nurse adhered to the then-effective MSR. This type of question is appropriate for the courts, not the FDA.

Second, CSL's argument that Scott's claims are preempted by FDA regulations and guidance also does not compel summary judgment on this record. CSL has not identified any law, regulation, or FDA guidance as of November 2008 that mandated that transgender donors were ineligible. The 1992 Recommendations state that "[p]ersons who have engaged in activities that put them at risk of HIV infection," such as men having sex with men or using intravenous drugs, "may not be donors." Willing Decl. Ex. O. Nothing in the 1992 Recommendations prevents a transgender woman who has never had sex with a man or participated in any of the other listed high-risk activities from donating. They further specify that in the screening process, the "focus should be on behavior and not on stereotypes." *Id.* The FDA also issued "Guidance for Industry" in 2006, which included endorsing an approved donor history questionnaire that collection centers could use to determine plasma donors' eligibility. The 2006 Guidance for Industry did not contain any express guidance regarding transgender donors, and moreover stated that its recommendations were nonbinding. The approved donor questionnaire also did not have any transgender-specific questions. There were three gender-specific questions, including one about pregnancy, but the FDA specified that the pregnancy question was optional, and the other two questions both concern whether a person has had sex

with a man, which would not have applied to Scott. *See* Willing Decl. Ex. R, Dkt. No. 58-3.⁴ Therefore, a finding that CSL unlawfully discriminated against Scott on the basis of her transgender status would not, as CSL argued, pose an inherent conflict with any law, regulation, or even FDA guidance in 2008.

In addition, most of CSL's preemption arguments rest, like its primary jurisdiction arguments, on the incorrect premise that a verdict for Scott would necessarily endanger CSL's current policy of rejecting all transgender donors. But CSL's current policy is not at issue on this motion. Rather, the record before this Court reveals a genuine issue of material fact as to why CSL rejected Scott and whether, had Corporate Medical Operations been involved, Scott would have been rejected.

CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Defendant's Motion for Summary Judgment [Docket No. 55] is DENIED.

Dated: December 3, 2015

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge

⁴ CSL also cited to minutes from the website of AABB, a trade group, purporting to summarize a May 29, 2009 meeting between FDA staff and AABB's FDA Liaison Committee. Willing Decl. Ex. Z, Dkt. No. 58-4. A proper foundation has not been laid for the Court to consider the truth of these minutes or CSL's understanding of them. Regardless, what the FDA may have said in May 2009 does not alter its regulations and recommendations as of November 2008.